UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,573	11/16/2000	Henryk Taper	TIENSERAFF.2	6030

7590 05/17/2004

Norman P Soloway
Hayes Soloway Hennessey Grossman & Hage
175 Canal Street
Manchester, NH 03101

EXAMINER	
FAY, ZOHREH A	

ART UNIT	PAPER NUMBER
1614	20

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/700,573	Applicant(s) TAPER ET AL.	
	Examiner Zohreh Fay	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-33 and 35-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-33 and 35-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 21-33 and 35-42 are presented for examination.

Claims 21-33 and 35-42 are rejected under 35 U.S.C. 102 (b) as being anticipated by European patent application 0692252. The European patent application teaches the use of insulin in combination with an antimetabolite with the claimed DP value for the treatment of cancer.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of certain cancers, does not reasonably provide enablement for " the treatment of cancer" in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered whether a disclosure meets the enablement requirement of 112 first paragraph, have been described in In re Wands, 8 USPQ 2d 1400 (Fed.Cir. 1988).

The court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdAPIs 1986) at 547 the court recited eight factors:

1.) the quantity of experimentation necessary,

2,) the amount of direction or guidance provided,

3.) the presence or absence of working examples

4.) the nature of the invention,

5.) the state of the prior art,

6.) the relative skill of those in the art,

7.) the predictability of the art, and

8.) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsection set forth herein below.

1. The nature of the invention, state of prior art, relative skill of those in the art and the predictability of the art.

The claimed invention relates to the treatment of cancer, and the art is high, generally that of a PHD or MD. This unpredictability has a number of facets as discussed hereinafter.

A. Treatment by cancer type

While the state of the art is relatively high with regard to the treatment of specific cancers with specific agents, it has long been underdeveloped with regard to the treatment of cancers broadly. In particular, there is no known anticancer agent which is effective against all cancers. This is why the National Cancer Institute (NCI) has the extensive in vitro drug screening. As discussed by the court in In re Brana, 51 F. 3d 1560 (Fed. Cir. 1995), in vitro assays are used by NCI (such as the p. 388 and L 1210 lymphocytic leukemia tests at issue therein) to measure the potential antitumor activity of a candidate compound. Brana at 1562-63. If success is shown in this initial

screening step, this demonstrates that at least one cancer type (e.g., lymphocytic leukemia) is sensitive thereto, and provides the incentive to select if for further studies to determine its usefulness as a chemotherapeutic agent against other cancer type.

Thus, a considerable amount of in vitro empirical testing is required with no prior expectation of success being present, before a candidate anticancer agent can be considered useful against any particular cancer type.

B. Combination Chemotherapy

Furthermore, the unpredictability observed is compounded when a combination of agents used. This is summarized by WO 00/61142, at page 1, lines 17-23.

Combination therapies while desirable, are a hit or miss proposition. The treatments are typically not additive. In many cases, cross effects and treatment load can result in lower effectiveness for the combination, than either treatment alone.

This is verified by U.S. Pat. 6,465,448 at col.1, lines 56-59.

2. The breadth of the claims

the claims are very broad and inclusive of "treatment of cancer" generally

3. the amount of direction or guidance provided and the presence or absence of working examples.

The specification provides no direction for ascertaining, which cancer will respond to the treatment.

4. The quality of experimentation necessary

The lack of adequate guidance from the specification or prior art with regard to the actual treatment of all cancers in a mammal with the claimed combination fails to rebut the presumption of unpredictability extent in this art. Applicant fails to provide guidance and information required to ascertain which particular type of cancer the claimed anticancer agents will be effective against without resorting to undue experimentation.

Absent a reasonable prior expectation of success for using a specific chemotherapeutic agent/combination to treat any particular type of cancer, one skilled in the art would have to extensively test many various tumor types.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is 308-4604. The examiner can normally be reached on Monday-Thursday 7:30 am -6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marrianne Cintins can be reached on 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Fay/tgd

January 13, 2004